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FISH & RICHARDSON P.C.
3300 DAIN RAUSCHER PLAZA
60 SOUTH SIXTH STREET
MINNEAPOLIS, MN 55402

EXAMINER	
HUYNH, PHUONG N	

ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/401,636	HELLMAN, LARS T.	
	Examiner	Art Unit	
	Phuong Huynh	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *Three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *01/08/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/12/04 has been entered.

2. Claims 25-40 are pending and are being acted upon in this Office Action.

3. Claim 37 is objected to because "dime effect" should have been "dimer effect".

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 25-26, 28-34, and 36-40 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling only for an immunogenic polypeptide comprising a non-self IgE CH2 domain, a self IgE CH3 domain, and a non-self IgE CH4 domain wherein the non-self CH2 and CH4 domains consists of an IgE sequence present in a non-placental mammal selected from the group consisting of opossum, platypus, koala, kangaroo, wallaby and wombat and wherein said immunogenic polypeptide is effective to induce an anti-self IgE response in a mammal for treating atopic allergies, **does not** reasonably provide enablement for *any* immunogenic polypeptide as set forth in claims 25-26, 28-34, and 36-40 for inducing any anti-self IgE response in any mammal. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in **scope** with these claims.

Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the lack of sufficient working examples, the unpredictability in the art and the amount of experimentation required to enable

one of skill in the art to practice the claimed invention. The specification disclosure is insufficient to enable one skilled in the art to practice the invention as broadly claimed without an undue amount of experimentation.

The specification discloses only immunogenic polypeptides such as the ones shown in Fig 2. The specification discloses immunogenic polypeptide comprising a self IgE CH3 domain located between a non-self IgE CH2 domain and a non-self CH4 domain wherein the non-self CH2 and CH4 domains are present in a non-placental mammal selected from the group consisting of opossum, platypus, koala, kangaroo, wallaby and wombat and wherein said immunogenic polypeptide is effective to induce an antiself IgE response (See page 3-4).

The specification does not teach how to make and use *any* immunogenic polypeptides mentioned above because there is insufficient guidance as to the structure without the amino acid sequence of any immunogenic polypeptide comprising a "self CH3 domain" from which mammal, and which one or more "non-self IgE domains" consists of which IgE sequence present in which non-placental mammal such as opossum, platypus, koala, kangaroo, wallaby and wombat and whether the immunogenic polypeptide is effective for inducing an anti-self IgE response (claim 25). Further, there is insufficient guidance as to the structure without the amino acid sequence of the "N-terminal half" of which self IgE CH3 domain in any immunogenic polypeptide (claim 33) because the term "N-terminal half" could be as little as 3 amino acids without specify the amino acid residues. In addition, it is not clear the "N-terminal half" is from which self IgE CH3 domain given the indefinite number of self IgE domain from all mammals.

Stryer *et al* teach that a protein is highly dependent on the overall structure of the protein itself and that the primary amino acid sequence determines the conformational of the protein (See enclosed appropriate pages).

Ngo *et al*, of record, teach that the amino acid positions within the polypeptide/protein that can tolerate change such as conservative substitution or no substitution, addition or deletion which are critical to maintain the protein's structure/function will require guidance (see Ngo et al., 1994, The Protein Folding Problem and Tertiary Structure Prediction, pp. 492-495).

Abaza *et al* teach that even a single amino acid substitution outside the antigenic site can exert drastic effects on the reactivity of a protein with monoclonal antibody against the site (See abstract, in particular).

Kuby *et al* teach that antibody epitopes (B cell epitopes) are not linear and are comprised of complex three-dimensional array of scattered residues which will fold into specific

conformation that contribute to binding (See Kuby 1994, page 94, in particular). Immunization with a peptide fragment derived from a full-length polypeptide may result in **antibody specificity** that differs from the antibody specificity directed against the native full-length polypeptide. Without the specific amino acid sequence of the immunogenic polypeptide, it is unpredictable which undisclosed immunogenic polypeptide is effective for generating antibody that is specific for the "self CH3 domain" and not the non-self IgE domains. Let alone the undisclosed polypeptide is capable of forming a soluble dimer (claims 29 and 37) given the ordering of CH2, CH3 and CH4 domain in the immunogenic polypeptide could be any combination and any one or more non-self domains such as CH2, CH3, CH4 from any non-placental mammal. Given the indefinite number of undisclosed immunogenic polypeptide, there is insufficient in vivo working example demonstrating that all immunogenic polypeptide is effective to induce an anti-self IgE response in any mammal such as human.

For these reasons, it would require undue experimentation of one skilled in the art to practice the claimed invention. See page 1338, footnote 7 of Ex parte Aggarwal, 23 USPQ2d 1334 (PTO Bd. Pat App. & Inter. 1992). In re wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988), the decision of the court indicates that the more unpredictable the area is, the more specific enablement is necessary. In view of the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims, it would take an undue amount of experimentation for one skilled in the art to practice the claimed invention.

Applicants' arguments filed 1/12/04 have been fully considered but are not found persuasive.

Applicants' position is that (1) claims 25 and 33 have been amended to recite that at least one of the non-self IgE domains consists of an IgE sequence present in a non-placental mammal. (2) As explained in the accompanying declaration by Dr. Hellman, a person having ordinary skill in the art would have been able to use common molecular biology technique to obtain IgE sequences from non-placental mammals.

In response, the specification discloses only immunogenic polypeptides such as the ones shown in Fig 2. The specification discloses immunogenic polypeptide comprising a self IgE CH3 domain located between a non-self IgE CH2 domain and a non-self CH4 domain wherein the non-self CH2 and CH4 domains are present in a non-placental mammal selected from the group

consisting of opossum, platypus, koala, kangaroo, wallaby and wombat and wherein said immunogenic polypeptide is effective to induce an antiself IgE response (See page 3-4).

The specification does not teach how to make and use *any* immunogenic polypeptides mentioned above because there is insufficient guidance as to the structure without the amino acid sequence of any immunogenic polypeptide comprising a "self CH3 domain" from which mammal, and which one or more "non-self IgE domains" consists of which IgE sequence present in which non-placental mammal such as opossum, platypus, koala, kangaroo, wallaby and wombat and whether the immunogenic polypeptide is effective for inducing an anti-self IgE response (claim 25). Further, there is insufficient guidance as to the structure without the amino acid sequence of the "N-terminal half" of which self IgE CH3 domain in any immunogenic polypeptide (claim 33) because the term "N-terminal half" could be as little as 3 amino acids without specify the amino acid residues. In addition, it is not clear the "N-terminal half" is from which self IgE CH3 domain given the indefinite number of self IgE domain from all mammals.

Abaza *et al* teach that even a single amino acid substitution outside the antigenic site can exert drastic effects on the reactivity of a protein with monoclonal antibody against the site (See abstract, in particular).

Kuby *et al* teach that antibody epitopes (B cell epitopes) are not linear and are comprised of complex three-dimensional array of scattered residues which will fold into specific conformation that contribute to binding (See Kuby 1994, page 94, in particular). Immunization with a peptide fragment derived from a full-length polypeptide may result in **antibody specificity** that differs from the antibody specificity directed against the native full-length polypeptide. Without the specific amino acid sequence of the immunogenic polypeptide, it is unpredictable which undisclosed immunogenic polypeptide is effective for generating antibody that is specific for the "self CH3 domain" and not the non-self IgE domains. Let alone the undisclosed polypeptide is capable of forming a soluble dimer (claims 29 and 37) given the ordering of CH2, CH3 and CH4 domain in the immunogenic polypeptide could be any combination and any one or more non-self domains such as CH2, CH3, CH4 from any non-placental mammal. Given the indefinite number of undisclosed immunogenic polypeptide, there is insufficient in vivo working example demonstrating that all immunogenic polypeptide is effective to induce an anti-self IgE response in any mammal such as human. Because of the lack of guidance as to the structure of immunogenic polypeptide, a person skill in the art would not have been able to make, much less

how to use any undisclosed immunogenic polypeptide for inducing anti-self IgE response in any mammal such as human.

6. Claims 25-26, 28-34, and 36-40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

The specification does not reasonably provide a **written description** of *any* immunogenic polypeptide as set forth in claims 25-26, 28-34, and 36-40 for inducing any anti-self IgE response in any mammal.

The specification discloses only immunogenic polypeptides such as the ones shown in Fig 2. The specification discloses immunogenic polypeptide comprising a self IgE CH3 domain located between a non-self IgE CH2 domain and a non-self CH4 domain wherein the non-self CH2 and CH4 domains are present in a non-placental mammal selected from the group consisting of opossum, platypus, koala, kangaroo, wallaby and wombat and wherein said immunogenic polypeptide is effective to induce an antiself IgE response (See page 3-4).

With the exception of the specific immunogenic polypeptide comprising SEQ ID NO: 8 or the ones shown in Fig 2, there is insufficient written description about the structure associated with function of *any* immunogenic polypeptide mentioned above because there is inadequate written description about the structure much less about the function without the amino acid sequence of any immunogenic polypeptide comprising a "self CH3 domain" from which mammal, and which one or more "non-self IgE domains" consists of which IgE sequence present in which non-placental mammal such as opossum, platypus, koala, kangaroo, wallaby and wombat and whether the immunogenic polypeptide is effective for inducing an anti-self IgE response (claim 25). Further, there is insufficient written description about the structure without the amino acid sequence of the "N-terminal half" of which self IgE CH3 domain in any immunogenic polypeptide (claim 33) because the term "N-terminal half" could be as little as 3 amino acids without specify the amino acid residues. In addition, it is not clear the "N-terminal half" is from which self IgE CH3 domain given the indefinite number of self IgE domain from all mammals. Without the specific amino acid sequence of the immunogenic polypeptide, it is clear which undisclosed immunogenic polypeptide is effective for generating antibody that is specific for the "self CH3 domain" and not the non-self IgE domains. Let alone the undisclosed

polypeptide is capable of forming a soluble dimer (claims 29 and 37) given the ordering of CH2, CH3 and CH4 domain in the immunogenic polypeptide could be any combination and any one or more non-self domains such as CH2, CH3, CH4 from any non-placental mammal. Given the indefinite number of undisclosed immunogenic polypeptide, there is insufficient in vivo working example demonstrating that all immunogenic polypeptide is effective to induce an anti-self IgE response in any mammal such as human.

Finally, the specification discloses only three IgE sequences from non-placental mammal such opossum, platypus and wombat, and given the divergent of IgE sequence of platypus from said other non-placental mammals, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus. *See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.*

Applicant is directed to the Final Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 103(a) that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 25-26, 28-34, and 36-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nissim *et al* (of record, EMBO J 10(1): 101-107, 1991; PTO 892) in view of WO9526356 publication (Oct 1995; PTO 892), Aveskogh *et al* (Eur J Immunol 28(9): 2738-50, PTO 892) and Hellman *et al* (in New Horizons in Allergy Immunotherapy, Plenum Press, New York, 1996, pages 337-342; PTO 892).

Nissim *et al* teach various immunogenic chimeric IgE polypeptide such as CHM3 wherein the reference polypeptide comprising a self IgE domain such as a mouse IgE CH3 domain and one or more non-self IgE domains such as human IgE CH1, CH2 and CH4 domains (See page 102, chimeric human-mouse IgE, Fig 1, page 103, column 1, first full paragraph, in

particular). The reference self IgE CH3 domain is located between the reference non-self IgE CH2 domain and said IgE CH4 domain (See Figure 1b, CHM3, in particular) and the Cys 328 is preserved to ensure proper dimerization (See page 4103, column 1, first full paragraph, in particular). The reference self IgE CH3 domain contains at least the N terminal half of the mouse IgE CH3 domain. Nissim *et al* teach that the entire C epsilon 3 domain in its native configuration is essential for binding of IgE molecule to the Fc epsilon receptor I while the C epsilon 2 domain plays an important role in the stabilization of the conformation of the FcεRI binding site via two interheavy chain disulfide bonds (See page 106, first full paragraph, in particular). Nissim *et al* teach that the advantage of knowing the receptor binding site is to design of IgE analogue that can be used to block the onset of allergic response or to regulate IgE production and several anti-IgE monoclonal antibodies are able to block the binding of IgE to mast cells effectively (See page 101, column 2, first paragraph, in particular).

The claimed invention in claims 25 and 33 differs from the teachings of the reference only that the immunogenic polypeptide comprising a self IgECH3 domain and one or more non-self IgE domains consisting of an IgE sequence present in a non-placental mammal wherein said immunogenic polypeptide is effective to induce an anti-self IgE response in a mammal.

The claimed invention in claims 26 and 34 differs from the teachings of the reference only that the immunogenic polypeptide is effective to induce anti-self IgE response in human.

The claimed invention as recited in claims 28 and 36 differs from the teachings of the reference only that the immunogenic polypeptide wherein said non-placental mammal is opossum.

The WO 9526356 publication teaches that the problem of almost all self-antigen such as IgE CH4 peptide is its weak immunogenicity (See page 15, line 19-22, in particular). The WO 9526356 publication further teaches that IgE peptide such as CH4 coupled to carrier protein is useful as a vaccine for generating antibodies that block the stimulatory action of IgE on mast cells and basophils and thereby prevent IgE-mediated allergic diseases (See page 15, lines 25-32, in particular). However, IgE from non-placental mammals such as opossum platypus, Koala, kangaroo, wallaby and wombat are the most evolutionary distantly related mammals to placental mammals such as humans and would be the most obvious choice as a source of distantly related non-self IgE for enhancing immunogenicity of the self IgE for inducing anti-self IgE response.

Aveskogh *et al* teach IgE from non-placental mammal such as opossum comprising various IgE domains such as IgE CH1, CH2, CH3, and CH4 domains (See abstract, Figure 1, in

particular). The reference IgE from non-placental mammal such as opossum is the most evolutionary distantly related mammals to placental mammals such as human and mice (see Figure 7, in particular) and would be the most obvious choice as a source of distantly related non-self IgE for enhancing immunogenicity of the self IgE for inducing anti-self IgE response.

Hellman *et al* teach a vaccination strategy by inducing a strong autoimmune antibody response against the patient's own circulating IgE using CH2 and CH3 domains of IgE coupled to foreign carrier (See page 338, last paragraph, in particular). Hellman *et al* teach that receptor binding region is located in the N-terminal part of the C3 domain and the entire CH2 and CH3 domains are used instead of short only short peptides from the N terminal region of the CH3 domain to obtain a larger number of surface epitopes and having these epitopes in close to native conformation (See page 339, first paragraph, in particular). Hellman *et al* further teach that in order to increase the immunogenicity of the polypeptide, the CH2-CH3 domain of IgE is fused to a foreign carrier such as S. japonicum GST polypeptide to circumvent the tolerance against the patient's own IgE (See page 339, in particular). Hellman *et al* teach that vaccination of the reference fusion protein is useful in decreasing serum IgE levels and blocking histamine release from mast cells and basophiles upon challenge with either a crosslinking polyclonal IgE or a specific allergen as a way to block the onset of allergic response (See page 337, Summary, in particular).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the non-self IgE domains from placental mammal as taught by Nissim *et al* for the IgE CH2 and CH4 domains from the most evolutionary distantly related non-placental mammals such as opossum as taught by Aveskogh *et al* for an immunogenic polypeptide comprising a self IgE CH3 located between a non-self IgE CH2 and CH4 domains from non-placental mammal such as opossum to enhance the immunogenicity of self IgE as taught by the WO9526356 publication, Nissum, Aveskogh et al and Hellman et al. Alternatively, it would have been obvious to substitute the IgE CH3 domain of opossum as taught by Aveskogh et al for the human IgE CH3 domain as taught by Hellman et al or the mouse IgE CH3 domain as taught by Nissum et al to overcome the problem of weak immunogenicity of almost all self-antigen such as IgE CH4 peptide as taught by the WO 9526356 publication for an immunogenic polypeptide comprising a self IgE CH3 domain or at least the N terminal half of a self IgE CH3 domain located between a non-self IgE CH2 and CH4 domains from non-placental mammal such as opossum to enhance the immunogenicity of self IgE as taught by the WO9526356 publication,

Nissum, Aveskogh et al and Hellman et al. From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

One of ordinary skill in the art at the time the invention was made would have been motivated to do this because the WO 9526356 publication teaches that the problem of almost all self-antigen such as IgE CH4 peptide is its weak immunogenicity (See page 15, line 19-22, in particular). Aveskogh *et al* teach that IgE from non-placental mammal such as opossum (See abstract, in particular) is the most evolutionary distantly related mammals to placental mammals such as human and mice (see Figure 7, in particular) and would be the most obvious choice as a source of distantly related non-self IgE for enhancing immunogenicity of the self IgE for inducing anti-self IgE response. Nissim *et al* teach that the entire C epsilon 3 domain in its native configuration is essential for binding of IgE molecule to the Fc epsilon receptor I while the C epsilon 2 domain plays an important role in the stabilization of the conformation of the FcεRI binding site via two interhveavy chain disulfide bonds (See page 106, first full paragraph, in particular). Nissim *et al* teach that anti-IgE monoclonal antibodies are able to block the binding of IgE to mast cells effectively (See page 101, column 2, first paragraph, in particular). Claim 26 is included in this rejection because the reference polypeptide would inherently induce anti-self IgE response in human because the constant region of opossum IgE is conserved among various mammalian epsilon chains (See page 2747, column 1, first full paragraph, in particular). Claim 29 is included in rejection because the reference immunogenic polypeptide inherently is capable of forming dimer because the cysteine Cys 328 is preserved to ensure proper dimerization as taught by Nissum et al (See page 4103, column 1, first full paragraph, in particular). Hellman *et al* teach a vaccination strategy by inducing a strong autoimmune antibody response against the patient's own circulating IgE using CH2 and CH3 domains of IgE is useful in decreasing serum IgE levels and blocking histamine release from mast cells and basophiles upon challenge with either a crosslinking polyclonal IgE or a specific allergen as a way to block the onset of allergic response (See page 337, Summary, in particular).

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.

Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 25-40 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 25-34, 36, 37, 39, 41-43, 45-49, 51 and 53 of copending Application No. 10/176,664.

All of pending claims are drawn to nearly the same immunogenic polypeptide.

Claim 25 of copending Application No. 10/176,664 recites An immunogenic polypeptide comprising a self IgE portion and a non-self IgE portion, wherein said immunogenic polypeptide is effective to induce an anti-self lgE response in a mammal, and wherein said non-self IgE portion comprises an IgE sequence present in a non-placental mammal (genus).

Claim 25 of instant application recites An immunogenic polypeptide comprising a self IgE CH3 domain and one or more non-self IgE domains wherein at least one of said non-self IgE domains consists of an IgE sequence present in a non-placental mammal and wherein said immunogenic polypeptide is effective to induce an anti-self IgE response in a mammal (species). An issuance of a patent to copending Application No. 10/176,664 (genus) would include the claims of instant application (a species).

Claim 26 of copending Application No. 10/176,664 recites the immunogenic polypeptide of claim 25, wherein said mammal is a human. Claim 26 of instant application recites the immunogenic polypeptide comprising a self IgE CH3 domain and one or more non-self IgE domains wherein at least one of said non-self IgE domains consists of an IgE sequence present in a non-placental mammal and wherein said immunogenic polypeptide is effective to induce an anti-self IgE response in human.

Claim 27 of copending Application No. 10/176,664 recites the immunogenic polypeptide of claim 25, wherein said self portion comprises at least a portion of a CH3 domain of IgE.

Claim 28 of copending Application No. 10/176,664 recites the immunogenic polypeptide of claim 27, wherein said self IgE portion lacks the CH2 domain of an IgE antibody.

Claim 29 of copending Application No. 10/176,664 recites the immunogenic polypeptide of claim 25, wherein said polypeptide is capable of dimerizing to form a soluble immunogenic dimer effective to induce said anti-self lgE response in said mammal. Claim 29 of instant application recites the immunogenic polypeptide of claim 25 wherein said polypeptide is capable of dimerizing to form a soluble immunogenic dimer effective to induce said anti-self lgE response in said mammal.

Claim 30 of copending Application No. 10/176,664 recites the immunogenic polypeptide of claim 25, wherein said non-self lgE portion comprises a first region and a second region, said self IgE portion being located between said first and second regions of said non-self lgE portion (genus) Claim 30 of instant application recites the immunogenic polypeptide comprising a self IgE CH3 domain and one or more non-self IgE domains consists of an IgE sequence present in a non-placental mammal wherein one of said non-self IgE domains is an IgE CH4 domain, and CH2 domain and wherein said self IgE CH3 domain is located between said IgE CH2 domain and said IgE CH4 domain and wherein said immunogenic polypeptide is effective to induce an anti-self IgE response in a mammal.

Claim 31 of copending Application No. 10/176,664 recites the immunogenic polypeptide of claim 30, wherein said first region comprises at least a portion of an IgE CH2 domain. Claim 31 of instant application recites the immunogenic polypeptide comprising a self IgE CH3 domain and one or more non-self IgE domains wherein one of said non-self IgE domain is an IgE CH2 domain present in a non-placental mammal and wherein said immunogenic polypeptide is effective to induce an anti-self IgE response in a mammal.

Claim 32 of copending Application No. 10/176,664 recites the immumogenic polypeptide of claim 30, wherein said second region comprises at least a portion of an lgE CH4 domain. Claim 32 of instant application recites the immunogenic polypeptide comprising a self IgE CH3 domain and one or more non-self IgE domains wherein one of said non-self IgE domain is an IgE CH4 domain present in a non-placental mammal and wherein said immunogenic polypeptide is effective to induce an anti-self IgE response in a mammal.

Claim 33 of copending Application No. 10/176,664 recites the immunogenic polypeptide of claim 25, wherein said non-placental mammal is selected from the group consisting of opossum, platypus, koala, kangaroo, wallaby, and wombat. Claim 28 of instant application

recites the immunogenic polypeptide comprising a self IgE CH3 domain and one or more non-self IgE domains wherein at least one of said non-self IgE domains consists of an IgE sequence present in a non-placental mammal selected from the group consisting of opossum, platypus, koala, kangaroo, wallaby, and wombat and wherein said immunogenic polypeptide is effective to induce an anti-self IgE response in a mammal.

Claim 34 of copending Application No. 10/176,664 recites the immunogenic polypeptide of claim 25, wherein said immunogenic polypeptide contains a eukaryotic post-translational modification. Since copending application is a continue application of instant application having the same specification, the immunogenic polypeptide of instant application inherently contains a eukaryotic post-translational modification.

Claim 35 of copending Application No. 10/176,664 recites the immunogenic polypeptide of claim 25, wherein said immunogenic polypeptide comprises a polyhistidine sequence. Since copending application 10/176,664 is a continue application of instant application having the same specification, the immunogenic polypeptide of instant application inherently contains polyhistidine sequence. In fact, SEQ ID NO: 8 in instant claim 35 contains the polyhistidine sequence.

Claim 36 of copending Application No. 10/176,664 recites the immunogenic polypeptide of claim 25, wherein said anti-self IgE response is a polyclonal response. Since copending application 10/176,664 is a continue application of instant application having the same specification, the polyclonal response of the immunogenic polypeptide of instant application is an inherent properties of the immunogenic polypeptide.

Claims 33 of instant recites An immunogenic polypeptide, comprising one or more non-self IgE domains: and at least an N-terminal half of a self IgE CH3 domain, wherein at least one of said non-self IgE domains ' consists of an IgE sequence present in a non-placental mammal, and wherein said immunogenic polypeptide is effective to induce an anti-self IgE response in a mammal (species).

Claims 34 of instant application recites the immunogenic polypeptide immunogenic polypeptide, comprising one or more non-self IgE domains: and at least an N-terminal half of a self IgE CH3 domain, wherein at least one of said non-self IgE domains consists of an IgE sequence present in a non-placental mammal, and wherein said immunogenic polypeptide is effective to induce an anti-self IgE response in human.

Claims 36 of instant application recites the immunogenic polypeptide immunogenic polypeptide, comprising one or more non-self IgE domains: and at least an N-terminal half of a self IgE CH3 domain, wherein at least one of said non-self IgE domains ' consists of an IgE sequence present in a non-placental mammal selected from the group consisting of opossum, platypus, koala, kangaroo, wallaby, and wombat, and wherein said immunogenic polypeptide is effective to induce an anti-self IgE response in mammal.

Claims 37 of instant application recites the immunogenic polypeptide immunogenic polypeptide, comprising one or more non-self IgE domains: and at least an N-terminal half of a self IgE CH3 domain, wherein at least one of said non-self IgE domains consists of an IgE sequence present in a non-placental mammal, wherein said polypeptide is capable of dimerizing to form a soluble immunogenic dime effective to induce said anti-self IgE response in said mammal.

Claims 38 of instant application recites the immunogenic polypeptide immunogenic polypeptide, comprising one or more non-self IgE domains: and at least an N-terminal half of a self IgE CH3 domain, wherein at least one of said non-self IgE domains consists of an IgE sequence present in a non-placental mammal wherein one of said non-self IgE domains is an IgE CH2 domain, wherein one of said non-self IgE domains is an IgE CH4 domain, and wherein said at least an N-terminal half of a self IgE CH3 domain is located between said IgE CH2 domain and said IgE CH4 domain and wherein said immunogenic polypeptide is effective to induce an anti-self IgE response in a mammal.

Claims 39 of instant application recites the immunogenic polypeptide immunogenic polypeptide, comprising one or more non-self IgE domains: and at least an N-terminal half of a self IgE CH3 domain, wherein at least one of said non-self IgE domains consists of an IgE sequence present in a non-placental mammal wherein one of said non-self IgE domains is an IgE CH2 domain and wherein said immunogenic polypeptide is effective to induce an anti-self IgE response in a mammal.

Claims 40 of instant application recites the immunogenic polypeptide immunogenic polypeptide, comprising one or more non-self IgE domains: and at least an N-terminal half of a self IgE CH3 domain, wherein at least one of said non-self IgE domains consists of an IgE sequence present in a non-placental mammal wherein one of said non-self IgE domains is an IgE CH4 domain and wherein said immunogenic polypeptide is effective to induce an anti-self IgE response in a mammal.

Although the pending claims of instant application and the claims of copending application USSN 10/176,664 are not identical, an issuance of a patent to copending Application No. 10/176,664 (genus) would include the claims of instant application (species).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. Claims 27 and 35 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chain can be reached on (571) 272-0841. The IFW official Fax number is (703) 872-9306.

14. Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phuong N. Huynh, Ph.D.
Patent Examiner
Technology Center 1600
March 8, 2004

Christina Chan

CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600